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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,435	10/16/2003	Geert Maertens	2551-130	5780

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NIXON & VANDERHYE, PC
1100 N GLEBE ROAD
8TH FLOOR
ARLINGTON, VA 22201-4714

EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 12/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/685,435	MAERTENS ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-25 and 28-56* is/are pending in the application.

4a) Of the above claim(s) *28,30,31 and 49-56* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24,25,29,32-48* is/are rejected.

7)☒ Claim(s) *23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/566,266.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10-16-2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, and the subinventions represented by SEQ ID NO: 15 in the reply filed on October 12, 2004 is acknowledged. The traversal is on the ground(s) that no restriction was made among the inventions in the prior application, which the Applicant notes was examined by the same Examiner. The Applicant additionally argues that the Examiner "has admitted that a separate search of this subject matter [of Groups I, III, V, and VII] will not be required." These arguments are not found persuasive.

It is first noted that the claims in the prior application were directed to a different claimed invention. Second, it is noted that, while the current Examiner did examine the prior application, the application had previously been acted on by a prior Examiner, and that the prior Examiner in that application exercised their discretion not to restrict among the inventions. In view of this, the prior decision not to restrict became binding in that case once a search and examination was performed on the claimed inventions in that case. However, this a new application, directed to a different claimed invention. As such, the current Examiner is free to exercise his discretion in the determination as to whether a restriction requirement is appropriate.

The Applicant also indicates that the Examiner has admitted that no separate searches for the claimed inventions would be required. They base this assertion on the common classification of the different inventions. However, the fact that the different inventions have a common classification is not conclusive evidence that no additional search is required for the different inventions. Two peptides that have no sequence identity, but both from the same virus (such as those in this case) may share a common classification. However, a proper search of the two

peptides would indubitably require separate searches, each of which would provide information relating to the patentability of only one of the peptides. Thus, separate searches would be required for each peptide claimed in the application. Further, the very fact that the Examiner saw fit to restrict between the inventions would indicate that the Examiner was of the opinion that additional searches would be required. This is because one requirement for making a restriction is that there must be a burden on the office in the examiner of the different inventions. Thus, if the Examiner felt that no additional search would be required, no restriction would have been made. There has therefore been no admission that no additional searches would be required.

With respect to the species election among the various sequences, it is noted that under the test of In re Harnisch, 206 USPQ 300 (CCPA 1980), the claimed sequences fail as a proper Markush Group. They share no common substantial structural feature. Thus, the sequences represent independent inventions (for which no generic linking claim has been provided). In such a case, where there is no allowable generic claim, there is no requirement to extend the search to additional species. See, MPEP 809.02.

For these reasons, the requirement is still deemed proper and is therefore made FINAL.

2. Claims 28, 30, 31, and 49-56 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on October 12, 2004.

3. Currently, claims 23-25, 29, and 32-48 are under consideration to the extent that the claims read on, or are generic to, peptides of SEQ ID NO: 15.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on October 16, 2003 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Sequence Listing

5. The specification is objected to for referring to protein or nucleic acid sequences without also identifying them by the sequence identifier assigned to them in the sequence listing as required by 37 CFR 1.821(d). See e.g., page 22, line 21; and page 25, lines 12 and 20. The examiner would like to bring the applicant's attention to the following excerpt from MPEP §2422.03:

> 37 CFR 1.821(d) requires the use of the assigned sequence identifier in all instances where the description or claims of a patent application discuss sequences regardless of whether a given sequence is also embedded in the text of the description or claims of an application. This requirement is also intended to permit references, in both the description and claims, to sequences set forth in the "Sequence Listing" by the use of assigned sequence identifiers without repeating the sequence in the text of the description or claims. Sequence identifiers can also be used to discuss and/or claim parts or fragments of a properly presented sequence. For example, language such as "residues 14 to 243 of SEQ ID NO: 23" is permissible and the fragment need not be separately presented in the "Sequence Listing." Where a sequence is embedded in the text of an application, it must be presented in a manner that complies with the requirements of the sequence rules.

The applicant is therefore required to amend the specification to comply with 37 CFR 1.821(d).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 24, 28, 29, 32-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. Claim 24 is treated as representative. This claim is directed to a peptide from the HCV E1 protein "consisting of up to 45 contiguous amino acids wherein an amino acid sequence" of SEQ ID NO: 15 is present in the peptide. It is not clear from the claim language if the claim is requiring that the full length peptide of SEQ ID NO: 15 is present in the peptide, or if the claim is intended to read on any peptide of up to 45 residues wherein the peptide comprises some contiguous sequence that may be found within SEQ ID NO: 15.

Clarification is required.

For the purposes of this action, the claim is being read as reading on any peptide of up to 45 residues that comprise some sequence that may be found within SEQ ID NO: 15. The "consisting of" language is read as excluding peptides of greater than 45 residues in length.

8. Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim reads on an assay kit comprising a peptide of SEQ ID NO: 15, wherein the kit is for "detecting the presence of anti-HCV-related virus antibodies." It is unclear what is meant by the term "anti-HCV-related virus antibodies." It is not clear if this term is intended to describe antibodies that are related to (i.e. that bind to) the HCV virus, or if the term is intended to identify antibodies that bind to the HCV virus or to related viruses. Clarification is required.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claim 29 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for kits comprising peptides of SEQ ID NO: 15 for the detection of anti-HCV antibodies, does not reasonably provide enablement for kits comprising this peptide for the detection of any "HCV-related virus." The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The claim has been described above. As indicated above, the language of the claim is unclear as to what is meant by the phrase "anti-HCV-related virus antibodies." For the purposes of this rejection, the claim is read as reading on a kit for the detection of antibodies against HCV, or against HCV-related viruses.

While the Applicant has shown that the peptide of SEQ ID NO: 15 is useful for the detection of antibodies against HCV, there is not identification of any other viruses, antibodies against which could be detected using the claimed peptide. There is no identification of either any virus sharing the sequence of SEQ ID NO: 15, nor any demonstration the peptide would be recognized by antibodies against any other viruses, Additionally, the sequence searches against the peptide did not locate any sequences in other virus sharing identity or close homology with the claimed peptide such that it would appear that the other virus would be recognized by antibodies that also recognize the peptide. In view of the lack of any guidance by the Applicant towards other viruses, the antibodies against which would recognize the indicated peptide, and the lack of teachings in the art identifying such viruses, the Applicant has not provided sufficient information to enable those in the art to use the claimed kits for the detection of antibodies against any virus other than HCV.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 24, 25, 29, 32-34, 36, 38, 40, 41, 43, 44, 45, 46, and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Maertens et al. (WO 96/04385- of record in the October 2003 IDS). The claims have been described above.

Maertens teaches a peptide comprising a sequence that may be found within SEQ ID NO: 15. Maertens, pages 21-22, and Table 3 on page 66. The reference also teaches compositions comprising the peptides, and kits comprising the peptides for the detection of anti-HCV antibodies. Page 27. The reference therefore anticipates the indicated claims..

13. Claims 24, 25, 29, 32-34, 36, 38, 40, 41, 43, 44, 45, 46, and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Dreesman et al. (WO 93/06488- of record in the October 2003 IDS). The claims have been described above.

Dreesman teaches a peptide sharing a sequence of contiguous amino acids with SEQ ID NO: 15. See, Table 3, page 75; Table 4, page 77; and SEQ ID NO: 18, page 132. The reference

also indicates that the peptide reacts with anti-HCV antibodies in some humans infected with HCV. Page 100. In view of this, the reference anticipates the indicated claims.

14. Claims 24, 25, 29, 32-34, 36, 38, 40, 41, 43, 44, 45, 46, and 47 are rejected under 35 U.S.C. 102(e) as being anticipated by Wang et al. (U.S. Patent 5,747,239- of record in the October 2003 IDS). The claims have been described above. Wang teaches a peptide for the detection of anti-HCV antibodies with a sequence of less than 45 residues and comprising a subsequence from SEQ ID NO: 15. See e.g., SEQ ID NO: 8 of the Patent (Table 8A, columns 43 and 44). The reference therefore anticipates the indicated claims.

15. Claims 24, 29, and 32-48 are rejected under 35 U.S.C. 102(e) as being anticipated by the '503 Patent (U.S. Patent 6,245,503, issued to Maertens et al.). The claims have been described above. The '503 Patent teaches a peptide (SEQ ID NO: 67), which is identical to the sequence disclosed in the Maertens reference above. The reference also teaches that the peptides may be biotinylated for use in assays. See e.g., column 20, lines 1-8. The reference therefore anticipates the indicated claims.

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. Claims 24, 25, 29, 32-34, 36, 38, 40, 41, 43, 44, 45, 46, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maertens et al. (WO 96/04385- or record in the October 2003 IDS), and further in view of either of Choo et al. (PNAS 88: 2451-55) or Zonara et al. (J Hepatol 21: 858-65). These claims read on peptides consisting of 21 to 33 residues of SEQ ID NO: 15, or to a peptide of up to 45 residues comprising a sequence within SEQ ID NO: 15, compositions thereof, and kits for the detection of anti HCV antibodies comprising the peptides. The teachings of Maertens have been described above. While the reference teaches a peptide homologous to a subsequence of SEQ ID NO: 15, the reference does not teach the peptide of SEQ ID NO: 15.

However, each of the Choo and Zonara references teach a protein sequence of other HCV isolates from those disclosed in Maertens. It would therefore have been obvious to those in the art to substitute peptides of the corresponding residues of the isolates from these references for the peptides disclosed in Maertens as functional equivalents. Such a substitution would result in a peptide corresponding to residues 7 to 26 of SEQ ID NO: 15. Additionally, the Maertens reference refers both to fragments of the E1 protein, and to fragments of the disclosed peptides.

Thus, it would have been obvious to those in the art that larger fragments of the E1 peptide comprising the indicated peptides could also be used. Because the Choo and Zonara references disclose sequences sharing 27 contiguous residues with SEQ ID NO: 15, and because the teachings of Maertens renders obvious the use of larger peptides comprising the disclosed peptides, the combined teachings of the references also render obvious the peptides of claim 25.

18. Claims 35, 37, 39, 42, 45, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of Dreesman, Wang, or Maertens in view of Choo as applied above, and further in view of De Leys et al. (WO 93/18054- of record in the October 2003 IDS). These claims further describe the claimed peptides as biotinylated. While the Dreesman reference, and the Maertens and Choo references teach the peptides of the indicated claims, they do not teach the biotinylation of the peptides.

However, the teachings of De Leys indicate that it was known in the art to use biotinylation of peptides as a means of improving the use of such peptides in immunological detection assays. See e.g., abstract, pages 2-3, and 5-7. From these teachings, in addition to the teachings of Maertens indicating that the disclosed peptides may be used in immunological assays, it would have been obvious to those in the art to use the processes of De Leys to make biotinylated peptides as required by the rejected claims. The combined teachings of these references therefore render the claimed invention obvious.

Conclusion

19. A claim drawn to the isolated peptide of SEQ ID NO: 15 would be allowable over the prior art. However, claim 23 is objected for reading on non-elected subject matter.

20. The following prior art referenced are made of record and considered pertinent to applicant's disclosure. However, while relevant they are also not used as a basis for rejection for the stated reasons.

> WO 93/06488 (of record in the October 2003 IDS). This reference teaches a peptide (SEQ ID NO: 18) comprising residues of a homologous region of the HCV E1 protein to SEQ ID NO: 15.
>
> WO 95/12677 (of record in the October 2003 IDS). This reference teaches a peptide of HCV E1 comprising a T-cell epitope wherein the protein comprises a sequence of between 21 and 33 residues of SEQ ID NO: 15. Page 17. However, the reference does not appear to teach or suggest a peptide consisting of such a sequence.
>
> U.S. Patent 5,882,852. This patent discloses the E1 sequence of a number of HCV isolates. See e.g., Figures 2 and 3. However, none of these comprises as sequence that shares 100% identity with SEQ ID NO: 15.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

JEFFREY STUCKER
PRIMARY EXAMINER